

## **REMARKS/ARGUMENTS**

Reconsideration and withdrawal of the rejections set forth in the Office Action dated May 7, 2003 are respectfully requested. A separate petition for a 3-month extension of time accompanies this amendment.

Claim 1 remains in this application. Claims 2-25 have been canceled.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 2-25 in a divisional application.

### **I. Amendments**

Claim 1 has been amended to incorporate the limitation found in dependent claim 2.

Sequence listing page 46 has been amended to include the sequences recited in Figure 2. A corresponding amendment to include the sequence identification numbers has been made to the specification.

No new matter has been added.

### **II. Rejection under 35 U.S.C. § 102(e)**

Claims 1-2 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,156,876 (Beach).

This rejection is respectfully traversed in view of the foregoing claim amendments and following remarks.

#### **A. The Invention**

The present invention, as embodied in amended claim 1, is directed to an isolated nucleic acid regulatory sequence for a cyclin D1 promoter. The regulatory sequence is represented by SEQ ID NO:5 and is characterized by the ability to regulate expression of a gene operably linked to a cyclin D1 promoter containing the regulatory sequence.

B. The Prior Art

Beach discloses the upstream promoter sequence of cyclin D1. Beach does not disclose an isolated nucleic acid regulatory sequence which

- (i) is represented by SEQ ID NO:5, and
- (ii) has the ability to regulate expression of a gene operably linked to a cyclin D1 promoter containing the regulatory sequence.

C. Analysis

For a prior art reference to be anticipating under Section 102, it must teach "each and every" element of the claimed invention. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). "Anticipation requires identity of invention: the claimed invention, as described in appropriately construed claims, must be the same as that of the reference, in order to anticipate." *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 33 USPQ2d 1496 (Fed. Cir. 1995).

Beach does not disclose isolated nucleic acid regulatory sequences for a cyclin D1 promoter. As noted above, beach merely discloses the promoter sequence itself. No guidance is given as to which regions of the promoter may be isolated and used as nucleic acid regulatory sequences. Therefore, Beach cannot anticipate the invention.

Furthermore, it is well established from the case law that a prior art reference which discloses a broad operating or composition range will not preclude patentability where the applicant's invention involves (i) a narrow range within the broadly disclosed range, and (ii) the narrow range discovered by the applicant is critical to achieving an unexpected result or property. See, e.g., (*Scandiamant Aktiebolag v. Comr. Pats.* (CADC 1974) 509 F2d 463, 184 USPQ 201; *In re Waymouth et al.* (CCPA 1974) 499 F2d 1273, 182 USPQ 290; *Ex parte Selby*, (POBA 1966) 153 USPQ 476).

In the present case, the applicants have shown that a regulatory sequence identified as SEQ ID NO: 5 is a critical target for achieving regulated gene expression.

Nowhere is the possibility of achieving this targeted regulation shown or suggested in Beach or any other art of which applicants are aware.

With regard to the overlap of the CRE region of the cyclin D1 promoter with SEQ ID NO:5, applicants direct the Examiner's attention to *Ex parte Thumm* (132 USPQ 66 POBA 1966). In *Ex parte Thumm* the court stated that "...although the two ranges overlap to a certain extent, such circumstance does not preclude the grant of a patent when the applicant satisfactorily establishes that he obtains results which are unobvious and unexpected and that his claims do not read upon a particular embodiment of the reference." As noted above, applicants' identification of the sequence represented by SEQ ID NO:5 as a target for regulated expression satisfactorily meets these requirements.

In view of the foregoing, the claims pending in the application patentably define over the prior art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 838-4405.

Respectfully submitted,

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Date: 11-5-03

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